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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

Bayer Schering Pharma AG and
Bayer Healthcare Pharmaceuticals Inc.,

Plaintiffs/Counterdefendants,

vs.

Lupin Limited

Defendant/Counterclaimant

and Lupin Pharmaceuticals, Inc.

Defendant

Case No. 2:10-cv-01166-GMN-RJJ

Bayer's Answer to Lupin's Counterclaims

1 Plaintiffs Bayer Schering Pharma AG and Bayer Healthcare Pharmaceuticals Inc.
2 (collectively "Bayer") respond as follows to the Counterclaims filed by Defendant Lupin Limited
3 ("Lupin Ltd."). (Doc. 10.) Answers to Lupin Ltd.'s specific allegations are contained below in
4 numbered paragraphs that correspond to the numbered paragraphs of Lupin Ltd.'s Counterclaims.
5 Bayer denies any allegations not expressly admitted in this Answer.

6 COUNTERCLAIMS

7 The unnumbered paragraph entitled "Counterclaims" contains prefatory language to
8 which no response is required. To the extent that this paragraph is deemed to contain factual
9 allegations, Bayer denies them.

10 THE PARTIES

- 11 1. Admitted.
12 2. Admitted.
13 3. Admitted.

14 BACKGROUND

15 4. On information and belief, Bayer admits that Defendants Lupin Ltd. and Lupin
16 Pharmaceuticals, Inc. (collectively, "Lupin") filed ANDA No. 20-1661 seeking approval to market
17 a generic version of Bayer's YAZ® oral contraceptive ("Lupin's YAZ® ANDA product"). Bayer
18 further admits that its YAZ® oral contraceptive is the subject of New Drug Application Nos. 21-
19 676, 21-873, and 22-045. Bayer is without knowledge to admit or deny any of the remaining
20 allegations in Paragraph 4.

21 5. Bayer admits that the patents listed in Paragraph 5 appear in the FDA's Orange
22 Book for NDA No. 21-676. The remainder of Paragraph 5 contains legal conclusions to which no
23 response is required. To the extent that the remainder of Paragraph 5 is deemed to contain factual
24 allegations, Bayer denies them.

25 6. Paragraph 6 contains legal conclusions to which no response is required. To the
26 extent that Paragraph 6 is deemed to contain factual allegations, Bayer denies them.

8. Bayer admits that Lupin sent Bayer a letter on June 2, 2010 providing notice that it had filed paragraph IV certifications for the patents identified in Paragraph 8. The remainder of Paragraph 8 contains legal conclusions to which no response is required. To the extent that the remainder of Paragraph 8 is deemed to contain factual allegations, Bayer denies them.

9. Bayer incorporates its above responses in response to Paragraph 9.
10. Paragraph 10 contains legal conclusions to which no response is required. To the extent that Paragraph 10 is deemed to contain factual allegations, Bayer denies them.
11. Paragraph 11 contains legal conclusions to which no response is required. To the extent that Paragraph 11 is deemed to contain factual allegations, Bayer denies them.
12. Paragraph 12 contains legal conclusions to which no response is required. To the extent that Paragraph 12 is deemed to contain factual allegations, Bayer denies them.
13. Admitted.

14. Bayer admits that it filed a complaint against Lupin on July 15, 2010, alleging infringement of U.S. Reissue Patent Nos. 27,564, 27,838, and 28,253 under 35 U.S.C. § 271(e). Otherwise denied.

16. Paragraph 16 contains legal conclusions to which no response is required. To the extent that Paragraph 16 is deemed to contain factual allegations, Bayer denies them.

Declaration of Invalidity of the '564 Reissue Patent

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SECOND CLAIM FOR RELIEF

Declaration of Noninfringement of the '564 Reissue Patent

26. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

26

27. Denied.

28. Paragraph 28 contains legal conclusions to which no response is required. To the extent that Paragraph 28 is deemed to contain factual allegations, Bayer denies them.

THIRD CLAIM FOR RELIEF

Declaration of Invalidity of the '838 Reissue Patent

29. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

29

30. Denied.

31. Paragraph 31 contains legal conclusions to which no response is required. To the extent that Paragraph 31 is deemed to contain factual allegations, Bayer denies them.

FOURTH CLAIM FOR RELIEF

Declaration of Noninfringement of the '838 Reissue Patent

32. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

32.

33. Denied.

34. Paragraph 34 contains legal conclusions to which no response is required. To the extent that Paragraph 34 is deemed to contain factual allegations, Bayer denies them.

FIFTH CLAIM FOR RELIEF

Declaration of Invalidity of the '253 Reissue Patent

35. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

35.

36. Denied.

1 37. Paragraph 37 contains legal conclusions to which no response is required. To the
2 extent that Paragraph 37 is deemed to contain factual allegations, Bayer denies them.

3 **SIXTH CLAIM FOR RELIEF**

4 **Declaration of Noninfringement of the '253 Reissue Patent**

5 38. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
6 38.

7 39. Denied.

8 40. Paragraph 40 contains legal conclusions to which no response is required. To the
9 extent that Paragraph 40 is deemed to contain factual allegations, Bayer denies them.

10 **SEVENTH CLAIM FOR RELIEF**

11 **Declaration of Invalidity of the '652 Patent**

12 41. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
13 41.

14 42. Denied.

15 43. Paragraph 43 contains legal conclusions to which no response is required. To the
16 extent that Paragraph 43 is deemed to contain factual allegations, Bayer denies them.

17 **EIGHTH CLAIM FOR RELIEF**

18 **Declaration of Noninfringement of the '652 Patent**

19 44. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
20 44.

21 45. Denied.

22 46. Paragraph 46 contains legal conclusions to which no response is required. To the
23 extent that Paragraph 46 is deemed to contain factual allegations, Bayer denies them.

24 **NINTH CLAIM FOR RELIEF**

25 **Declaration of Invalidity of the '338 Patent**

26 47. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
27 47.

1 48. Denied.

2 49. Paragraph 49 contains legal conclusions to which no response is required. To the
3 extent that Paragraph 49 is deemed to contain factual allegations, Bayer denies them.

4 **TENTH CLAIM FOR RELIEF**

5 **Declaration of Noninfringement of the '338 Patent**

6 50. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
7 50.

8 51. Denied.

9 52. Paragraph 52 contains legal conclusions to which no response is required. To the
10 extent that Paragraph 52 is deemed to contain factual allegations, Bayer denies them.

11 **ELEVENTH CLAIM FOR RELIEF**

12 **Declaration of Invalidity of the '395 Patent**

13 53. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
14 53.

15 54. Denied.

16 55. Paragraph 55 contains legal conclusions to which no response is required. To the
17 extent that Paragraph 55 is deemed to contain factual allegations, Bayer denies them.

18 **TWELFTH CLAIM FOR RELIEF**

19 **Declaration of Noninfringement of the '395 Patent**

20 56. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph
21 56.

22 57. Denied.

23 58. Paragraph 58 contains legal conclusions to which no response is required. To the
24 extent that Paragraph 58 is deemed to contain factual allegations, Bayer denies them.

THIRTEENTH CLAIM FOR RELIEF

Declaration of Invalidity of the '326 Patent

59. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

59.

60. Denied.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent that Paragraph 61 is deemed to contain factual allegations, Bayer denies them.

FOURTEENTH CLAIM FOR RELIEF

Declaration of Noninfringement of the '326 Patent

62. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

62.

63. Denied.

64. Paragraph 64 contains legal conclusions to which no response is required. To the extent that Paragraph 64 is deemed to contain factual allegations, Bayer denies them.

FIFTEENTH CLAIM FOR RELIEF

Declaration of Invalidity of the '931 Patent

65. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph

65.

66. Denied.

67. Paragraph 67 contains legal conclusions to which no response is required. To the extent that Paragraph 67 is deemed to contain factual allegations, Bayer denies them.

SIXTEENTH CLAIM FOR RELIEF

Declaration of Noninfringement of the '931 Patent

68. Bayer incorporates its above responses to Paragraphs 1-22 in response to Paragraph 68.

69. Denied.

PRAYER FOR RELIEF

DATED: October 21, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(b), I certify that on October 21, 2010, I caused a true and correct copy of the foregoing to be transmitted electronically through the Court's e-filing electronic notice system following counsel of record:

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